



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,570	03/09/2001	William R. Fiehler	S-8165-CON	6856

7590

04/10/2002

BROWN RUDNICK FREED & GESMER
One Financial Center
18th Floor, BOX 1P
BOSTON, MA 02111

EXAMINER

KIM, SUN U

ART UNIT	PAPER NUMBER
----------	--------------

1723

DATE MAILED: 04/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/803,570

Applicant(s)

FIEHLER, WILLIAM R.

Examiner

John Kim

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 14 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 15-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 15-25, 27, 28 and 30 is/are rejected.
- 7) ☒ Claim(s) 26, 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1723

1. Claims 1-6, 11 and 14-20 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,257,886 (hereinafter referred to as Kessler). Kessler teaches a blood - collection device comprising a tube (10) with a hydrophobic coating (30) on the inner surface of the tube and thixotropic gel material (28) placed in a bottom inner central surface of the tube (10) with a syringe (see figures 1-3; col. 2, line 46 - col. 6, line 21). Kessler teaches that generally lower 40 to 60 percent of the length of the inner surface of the container will normally need to be coated with hydrophobic material in order to provide an adjacent hydrophobic surface for the barrier material and the heavier portion of the blood (see col. 5, lines 3-11). Hydrophobic coating is a non-stick coating for hydrophilic component of blood. The limit of where the gel can be placed are in the range shown by Kessler.

2. Claims 21-25 and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kessler. Kessler teaches the method of placing blood in the above described tube and centrifuging blood (see figures 1-3). Furthermore, Kessler teaches that any means used to place the gel in the container adjacent the closed end of the tube is satisfactory so long as a transverse barrier is formed between the separated phase of the blood upon centrifugation of the device (see col. 3, lines 29-37). Claims 21-25 and 27-28 essentially differ from the method of Kessler in reciting providing dispensing apparatus including claimed predetermined first and second limits to dispense gel along a portion of central inner surface of the collection tube. Kessler teaches that generally lower 40 to 60 percent of the length of the inner surface of the container will normally need to be coated with hydrophobic material in order to provide an adjacent hydrophobic surface for the barrier material and the heavier portion of the blood (see col. 5, lines 3-11). Defining the limits of gel to be placed in the tube would have been obvious to a person of

Art Unit: 1723

ordinary skill in the art depending on the volume of blood to be separated and limitations set by hydrophobic coating on the tube of Kessler.

3. Claims 7-10 and 30 (independently) are rejected under 35 U.S.C. 103(a) as being unpatentable over Kessler as applied to claim 5 above, and further in view of U.S. Patent No. 3,516,385 (Walling). Claims 7-10 and 30 essentially differ from the apparatus of Kessler in reciting a dispensing apparatus having a nozzle with a plurality of openings disposed about a portion of a circumference thereof through which gel is dispensed. Kessler teaches that any means used to place the gel in the container adjacent the closed end of the tube is satisfactory so long as a transverse barrier is formed between the separated phase of the blood upon centrifugation of the device (see col. 3, lines 29-37). Walling teaches that coating materials are coated in the interior of tubular members by a centrifugal distributor with nozzle having a plurality of openings disposed about a portion of a circumference thereof and the number and size of the openings and the speed of a lancer holding the centrifugal distributor will determine the thickness of the coating and inherently the shapes of the coating (see col. 7, line 41 - col. 9, line 50). It would have been obvious to a person of ordinary skill in the art to use the known coating apparatus having a nozzle with a plurality of openings to coat the inner surface of a tube with gel for separating blood components.

4. Claims 1-4, 12-14, 16 and 18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,853,600 (hereinafter referred to as McNeal et al). McNeal et al teach a blood collection device comprising a tube (10) and thixotropic gel material (24) placed on the inner surface of the tube (10) in a form of discrete stripes or continuous bands (see figures 1-6, col. 2, line 60 - col. 4, line 46). McNeal et al teach the method of placing blood in the above

Art Unit: 1723

described tube and centrifuging blood (see figures 1-6).

5. Claims 26 and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. Applicant's arguments with respect to claims 1-11 and 14-30 have been considered but are moot in view of the new ground(s) of rejection.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (703) 308-2350. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

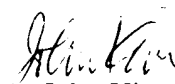
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (703) 308-0457. The fax phone number for

Art Unit: 1723

official response after final action is (703) 305-3599, and the fax phone number for all other official faxes is (703) 305-7718.

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.



John Kim
Primary Examiner
Art Unit 1723

J. Kim
April 8, 2002